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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,371	08/22/2001	Haruo Onda	44168-DIV4 (70281)	1969
21874	7590	05/06/2004	EXAMINER	
EDWARDS & ANGELL, LLP			WEDDINGTON, KEVIN E	
P.O. BOX 55874			ART UNIT	
BOSTON, MA 02205			PAPER NUMBER	
			1614	

DATE MAILED: 05/06/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/935,371

Applicant(s)

ONDA ET AL.

Examiner

Kevin E. Weddington

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-40 and 51-56 is/are pending in the application.
- 4a) Of the above claim(s) 37, 38 and 54-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39, 40 and 51-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 02/19/02.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

CLAIMS 37-40 AND 51-56 ARE PRESENTED FOR EXAMINATION.

APPLICANTS' PRELIMINARY AMENDMENT FILED AUGUST 22, 2001 AND THE INFORMATION DISCLOSURE STATEMENT FILED FEBRUARY 19, 2002 HAVE BEEN RECEIVED AND ENTERED.

APPLICANTS' ELECTION FILED AUGUST 13, 2003 IN RESPONSE TO THE RESTRICTION REQUIREMENT OF JULY 10, 2003 HAS BEEN RECEIVED AND ENTERED. THE APPLICANTS ELECTED THE INVENTION DESCRIBED IN CLAIMS 39, 40 AND 51-53 (GROUP I) WITHOUT TRAVERSE.

CLAIMS 37, 38 AND 54-56 ARE WITHDRAWN FROM CONSIDERATION AS BEING DRAWN TO THE NON-ELECTED INVENTION (37 CFR 1/142(B)).

CLAIM REJECTIONS - 35 USC § 112

THE FOLLOWING IS A QUOTATION OF THE FIRST PARAGRAPH OF 35 U.S.C. 112:

THE SPECIFICATION SHALL CONTAIN A WRITTEN DESCRIPTION OF THE INVENTION, AND OF THE MANNER AND PROCESS OF MAKING AND USING IT, IN SUCH FULL, CLEAR, CONCISE, AND EXACT TERMS AS TO ENABLE ANY PERSON SKILLED IN THE ART TO WHICH IT PERTAINS, OR WITH WHICH IT IS MOST NEARLY CONNECTED, TO MAKE AND USE THE SAME AND SHALL SET FORTH THE BEST MODE CONTEMPLATED BY THE INVENTOR OF CARRYING OUT HIS INVENTION.

CLAIMS 39, 40 AND 51-53 ARE REJECTED UNDER 35 U.S.C. 112, FIRST PARAGRAPH, AS FAILING TO COMPLY WITH THE ENABLEMENT REQUIREMENT. THE CLAIM(S) CONTAINS SUBJECT MATTER WHICH WAS NOT DESCRIBED IN THE SPECIFICATION IN SUCH A WAY AS TO ENABLE ONE SKILLED IN THE ART TO WHICH IT PERTAINS, OR WITH WHICH IT IS MOST NEARLY CONNECTED, TO MAKE AND/OR USE THE INVENTION.

APPLICANTS' SPECIFICATION DOES NOT POINT OUT OR IDENTIFY THE COMPOUNDS USED IN THE PHARMACEUTICAL COMPOSITION. THE SPECIFICATION DOES NOT POINT OUT OR IDENTIFY A COMPOUND OR A SALT THEREOF, WHICH ACTIVATED A PACAP RECEPTOR OR ANTAGONIZES BINDING OF PACAP TO A PACAP RECEPTOR.

CLAIM 39, 40 AND 51-53 ARE NOT ALLOWED.

CLAIM REJECTIONS - 35 USC § 112

THE FOLLOWING IS A QUOTATION OF THE SECOND PARAGRAPH OF 35 U.S.C. 112:

THE SPECIFICATION SHALL CONCLUDE WITH ONE OR MORE CLAIMS PARTICULARLY POINTING OUT AND DISTINCTLY CLAIMING THE SUBJECT MATTER WHICH THE APPLICANT REGARDS AS HIS INVENTION.

CLAIMS 39, 40 AND 51-35 ARE REJECTED UNDER 35 U.S.C. 112, SECOND PARAGRAPH, AS BEING INDEFINITE FOR FAILING TO PARTICULARLY POINT OUT AND DISTINCTLY CLAIM THE SUBJECT MATTER WHICH APPLICANT REGARDS AS THE INVENTION.

CLAIMS 39, 40 AND 51-53 ARE RENDERED INDEFINITE AND VAGUE BECAUSE IN CLAIM 39, THE APPLICANTS DO NOT DISCLOSE OR IDENTIFY THE COMPOUND USED IN THE PHARMACEUTICAL COMPOUND AND CLAIM 39 IS WRITTEN LIKE A METHOD CLAIM (A TEST) WHICH IS CONFUSING. CLAIMS 51-53 ARE RENDERED INDEFINITE BECAUSE THE CLAIMS DO NOT IDENTIFY A COMPOUND OR A PACAP AGONIST.

CLAIMS 39, 40 AND 51-53 ARE NOT ALLOWED.

CLAIM REJECTIONS - 35 USC § 102

THE FOLLOWING IS A QUOTATION OF THE APPROPRIATE PARAGRAPHS OF 35 U.S.C. 102 THAT FORM THE BASIS FOR THE REJECTIONS UNDER THIS SECTION MADE IN THIS OFFICE ACTION:

A PERSON SHALL BE ENTITLED TO A PATENT UNLESS -

(A) THE INVENTION WAS KNOWN OR USED BY OTHERS IN THIS COUNTRY, OR PATENTED OR DESCRIBED IN A PRINTED PUBLICATION IN THIS OR A FOREIGN COUNTRY, BEFORE THE INVENTION THEREOF BY THE APPLICANT FOR A PATENT.

CLAIMS 39 AND 51-53 ARE REJECTED UNDER 35 U.S.C. 102(A) AS BEING ANTICIPATED BY ARIMURA ET AL. (5,128,242).

ARIMURA ET AL. TEACH PEPTIDES HAVING ADENYLATE CYCLASE STIMULATING ACTIVITY OR WELL-KNOWN AS PACAP RECEPTORS. NOTE PARTICULARLY CLAIM 1 OF THE REFERENCE DISCLOSES THE PACAP RECEPTORS OR COMPOUNDS THAT ARE EXACTLY THE SAME AS THE APPLICANTS' COMPOUNDS. SINCE THE APPLICANTS ARE CLAIMING A COMPOUND, WHICH READS ON THE COMPOUND ALONE, THEN THE CITED REFERENCE ANTICIPATES THE INSTANT INVENTION.

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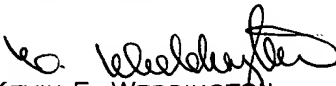
APPLICANTS ARE NOT ENTITLED TO PROCURE CLAIMS BASED ON DISCOVERY THAT WELL-KNOWN AND OLD COMPOUNDS CAN BE ADAPTED TO NEW USES; TO ENTITLE HIM TO A PATENT, THE COMPOUNDS MUST BE BOTH NEW AND UNOBVIOUS TO ONE SKILLED IN THE ART. (SEE IN RE HACK 114 USPQ 161)

CLAIMS 39 AND 51-53 ARE NOT ALLOWED.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO KEVIN E. WEDDINGTON WHOSE TELEPHONE NUMBER IS (571) 272-0587. THE EXAMINER CAN NORMALLY BE REACHED ON 11:00 AM-7:30 PM.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, MARRIANNE SEIDEL CAN BE REACHED ON (703) 308-1235. THE FAX PHONE NUMBER FOR THE ORGANIZATION WHERE THIS APPLICATION OR PROCEEDING IS ASSIGNED IS 703-872-9306.

INFORMATION REGARDING THE STATUS OF AN APPLICATION MAY BE OBTAINED FROM THE PATENT APPLICATION INFORMATION RETRIEVAL (PAIR) SYSTEM. STATUS INFORMATION FOR PUBLISHED APPLICATIONS MAY BE OBTAINED FROM EITHER PRIVATE PAIR OR PUBLIC PAIR. STATUS INFORMATION FOR UNPUBLISHED APPLICATIONS IS AVAILABLE THROUGH PRIVATE PAIR ONLY. FOR MORE INFORMATION ABOUT THE PAIR SYSTEM, SEE [HTTP://PAIR-DIRECT.USPTO.GOV](http://PAIR-DIRECT.USPTO.GOV). SHOULD YOU HAVE QUESTIONS ON ACCESS TO THE PRIVATE PAIR SYSTEM, CONTACT THE ELECTRONIC BUSINESS CENTER (EBC) AT 866-217-9197 (TOLL-FREE).


KEVIN E. WEDDINGTON
PRIMARY EXAMINER
ART UNIT 1614

K. WEDDINGTON
APRIL 30, 2004